

REMARKS

Claims 8, 9 and 16-23 are pending in the instant application and under consideration.

I. The Amendments

The claims have been amended, without prejudice, for the purpose of more clearly defining what the Applicants regard as the invention and for placing the rejected claims in condition for allowance. The amendments do not add new matter and are fully supported in the application as originally filed. Therefore, entry of the amendments under 37 C.F.R. § 1.111 is respectfully requested.

II. The Rejections

A. The Rejection Of Claims 8, 9, 16-18, And 21 Under 35 U.S.C. § 101

Claims 8, 9, 16-18, and 21 are rejected under 35 U.S.C. § 101 because the claimed subject matter allegedly is not supported by either a credible asserted utility or a well-established utility. The rejection is respectfully traversed.

It is well established that an asserted utility creates a presumption of utility. *See*, MPEP 2107.02, *citing In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 213-13 (CCPA 1977). As the Court of Customs and Patent Appeals stated in *In re Langer*:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d at 1391, 183 USPQ at 297 (emphasis in original).

In the present case, the asserted utility for the claimed method is the use of the disclosed protease-related protein for the negative regulation of keratinization of hair, *i.e.*, a reduction of normal or strong keratinization of hair. This asserted utility is based on the observation that in nude whn (-/-) mice, there is correlation between overexpression of protease-related protein, and underexpression of the known keratins Ha3 and CK15, both known to be required for hair growth. Thus, it can be reasonably expected that overexpression of protease-related protein promotes the lack of hair. The Examiner has not shown any evidence that the asserted utility is not credible and, as such, has not met his burden to rebut the presumption of utility.

In view of the above, the rejection under 35 U.S.C. § 101 is in error and should be withdrawn.

B. The Rejection Of Claims 8, 9, 16-18 And 21 Under 35 U.S.C. § 112, First Paragraph

Claims 8, 9, 16-18, and 21 are rejected under 35 U.S.C. § 112, first paragraph, because allegedly one skilled in the art would not know how to use the claimed invention in light of the asserted lack of utility. This rejection is respectfully traversed.

Given that the claimed invention has asserted utility and, as such, utility is presumed, *see supra*, the stated basis for this rejection is lacking. Therefore, it should be withdrawn.

In a second aspect, Claims 8, 9, 16, 17, and 18 are rejected because they encompass any nucleotide sequence which hybridizes to SEQ ID NO:1 at 20°C below the DNA melting which allegedly is not enabled in the specification. Applicants respectfully disagree.

The specification teaches that administration of the protease-related protein of the invention (in the form of protein or as nucleic acid encoding and expressing the same) leads to a downregulation of keratinization of hair. *See*, Substitute Specification, at page 2, lines 19-26 and page 5, lines 6-14. Downregulation of keratinization of hair can be readily

detected in the changed chemical composition of hair. Moreover, downregulation of keratinization will ultimately lead to hair loss, which can be readily detected. Thus, there are tests available to determine whether a protein comprising amino acid or base pair additions, deletions or substitutions relative to the amino acid sequence of SEQ ID NO:2 would be a protease-related protein according to the present invention. Thus, one skilled in the art would be able to determine without undue experimentation whether a particular sequence variant could be used for the methods and compositions presently claimed. Accordingly, the recited sequence variations of the protease-related proteins of the invention are enabled, and this aspect of the rejection under 35 U.S.C. § 112, first paragraph is in error and should be withdrawn.

Finally, in a third aspect of the rejection for lack of enablement, the Examiner alleges that since there are no *in vivo* working examples in the specification as filed to demonstrate the “negative regulation of the keratinization of hair” by administering protease-related protein, it is not clear that the claimed method is enabled. Applicants respectfully disagree.

In the specification the Applicants teach that there is a causal relationship between the presence of protease-related protein and the absence of hair. Specifically, the Applicants teach that protease-related protein is upregulated in nude whn (-/-) mice. The Applicants found that the absence of the whn gene results in upregulation of protease-related protein, while the expression of keratin, encoded by Ha3 and CK15, is downregulated. Thus, it can be concluded that the upregulation of PVP is promoting the lack of hair.

Applicants wish to point out that *in vivo* data are not required to meet the enablement requirement of Section 112, first paragraph. The legal standard for usefulness and enablement of a claimed invention does not require that the Applicant for a patent shows safety and efficacy of a compound in humans. It is the purpose of Phase II clinical studies that have been authorized by the FDA to make this determination. Indeed, as the Federal

Circuit cautions in *In re Brana, supra*, “[w]ere we to require Phase II testing in order to prove utility¹, the associated costs would prevent companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.” Thus, this aspect for a rejection for lack of enablement is improper and should be withdrawn.

In view of the above, the rejection under 35 U.S.C. § 112, first paragraph should be withdrawn.

C. The Rejection of Claims 8, 9, 16-18, and 21 Under 35 U.S.C. § 112, Second Paragraph

Claims 8, 9, 18, and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is in part obviated and/or overcome in view of the amendments to the claims, and in part traversed.

First, the phrase “a protease-related protein” in Claims 8, 9, 18, and 21 is objected to as being indefinite because “the phrase is not known.” This rejection is obviated and/or overcome in view of the amendment to Claim 8 and should therefore be withdrawn.

Second, the phrase “hybridizes to SEQ ID NO:1 at 20 °C below the DNA melting” in Claims 8, 16 and 17 is objected to because specific hybridization conditions are not recited and the phrase “below the DNA melting” is not known. With regard to Claims 16 and 17 this rejection this rejection is obviated and/or overcome in view of the amendments to those claims. With regard to Claim 8, the rejection is traversed.

Applicants wish to point out that one skill in art would readily know what hybridization conditions to use to obtain the nucleic acids falling under the recited claim

¹ Although the court refers to utility, the court argument was made in the context of a rejection under 35 U.S.C. § 112, first paragraph, as in the present case.

limitation. As such, this basis for a rejection under Section 112, second paragraph is improper, and should be withdrawn.

Third, the phrase “having a different nucleotide composition due to the degenerated genetic code” is objected to as rendering the claim indefinite. This rejection is obviated and/or overcome in view of the amendment to the claims.

Finally, Claims 8, 9, 16-18, and 21 are rejected as being incomplete for omitting essential steps. This rejection is obviated and/or overcome in view of the amendment to the claims.

In view of the above, the rejection under 35 U.S.C. 112, second paragraph should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (415) 781-1989. The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-2319 (Order No. 33999/US (473299-39) BM) for

any matter in connection with this response, including any fee for extension of time, which may be required.

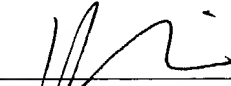
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Respectfully submitted,

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